

CLINICAL STUDY

Effect of acupuncture anesthesia on acne vulgaris of pricking-blood-letting cupping: a single-blind randomized clinical trial

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RESULTS: There were differences in the VAS scores of pain on pricking and in the pricked area, and the duration of pain between the groups. After 12 treatments, there was a significant reduction in GAGS scores from baseline in both groups, but there was no significant difference between the groups.

CONCLUSION: Acupuncture anesthesia at Hegu (LI 4) and Quchi (LI 11) is an effective means of alleviating the pain of pricking-bloodletting cupping and reducing the duration of pain in the treatment area. Pricking-bloodletting cupping at Dazhui (GV 14) improves the skin lesions of patients with moderate acne vulgaris, but acupuncture anesthesia does not appear to have an additional therapeutic effect.

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Key words: Acupuncture anesthesia; Bloodletting therapy; Acne vulgaris; Single-blind method; Randomized controlled trial; Point Dazhui (GV 14); Point Hegu (LI 4); Point Quchi (LI 11)

Abstract

OBJECTIVE: To evaluate the effect on acne vulgaris of pricking-bloodletting cupping at Dazhui (GV 14) under acupuncture anesthesia, and establish whether providing anesthesia to the treatment area by manipulating Hegu (LI 4) and Quchi (LI 11) might have an additional therapeutic benefit.

METHODS: Thirty-eight patients were recruited and randomized into a control group and an intervention group with a single-blind (observer-blind) method. The control group was treated by pricking-bloodletting cupping at Dazhui (GV 14) and the studied group by pricking-bloodletting cupping at Dazhui (GV 14) under acupuncture anesthesia at Hegu (LI 4) and Quchi (LI 11). Both groups were treated twice weekly for 6 weeks. The analgesic and therapeutic effects of acupuncture were evaluated on a visual analog scale (VAS) and global acne grading system (GAGS), respectively.

INTRODUCTION

Acne vulgaris is a chronic dermatosis caused by inflammation of pilosebaceous units in the skin, which often occurs on the face, chest and back. It is caused by over secretion of androgens, dyskeratosis of conduits in the sebaceous gland, and microbial infection.¹ Acne vulgaris is common in adolescence and may continue into adulthood.² Acne falls into the category of "acne (Fenci)" and "acne frontalis (Mianpao)" in Chinese Medicine. Several preliminary studies have suggested that pricking-bloodletting cupping at Dazhui (GV 14) is an effective means of treating acne vulgaris, to such an extent that Dazhui (GV 14) is sometimes referred to as

the "acne point" in the literature.³⁻⁵ Clinicians usually use a three-edged needle to prick or the plum-blossom needle to tap Dazhui (GV 14) and subsequently undertake bloodletting cupping. The procedure is uncomfortable and as a result many patients refuse to undergo it, but acupuncture anesthesia may address this problem. We designed a clinical trial to examine the effect of acupuncture anesthesia on the pain of pricking-bloodletting cupping and plum-blossom needle tapping.

Pricking with a three-edged needle was applied at Dazhui (GV 14) followed by bloodletting cupping. Hegu (LI 4) and Quchi (LI 11) were selected for acupuncture anesthesia,⁶ which are also important points for the treatment of acne vulgaris.⁷ The analgesic effects were measured and compared with that of the control group in which no acupuncture anesthesia was provided, but we also examined whether manipulation of Hegu (LI 4) and Quchi (LI 11) had an additional therapeutic benefit for acne vulgaris.

METHODS

Subjects

Participants were students from Ningxia Medical University. They were recruited via Intranet and poster advertisements at the University. Conduct of the study was approved by the research ethics committee of the General Hospital of Ningxia Medical University. After an explanation of the study procedures, each participant signed written informed consent. Informed consent was given by parents or guardians for participants under the age of 18 years. Participants were required to abstain from other acne treatments for the duration of the study, and the use of cosmetics or sunglasses was not allowed.

Inclusion criteria

Between May 2010 and December 2012, 38 of 70 applicants were enrolled who met the following criteria: (a) 17-26 years of age; (b) a total global acne grading system (GAGS) score in the range 8-30 (GAGS grade 1 and 2 as shown in Table 1); and (c) a diagnosis of acne vulgaris that had persisted for >3 months (chronic stage).

Exclusion criteria

Patients were excluded if they: (a) had abnormal routine and coagulation blood tests; (b) had received any

medical treatment for acne within 1 month of study entry, such as Western medical treatment (for example retinoids, antibiotics, chemical peeling, intense pulsed light, or laser treatment) or Chinese Medicine treatment (for example acupuncture, moxibustion, or herbal medicine); (c) were pregnant; (d) had been diagnosed with other infectious skin diseases or internal diseases that needed treatment without delay; and (e) did not comply with the study guidelines.

Design of study

The study was a randomized controlled clinical trial. After enrollment, participants were randomized into one of two groups according to a random number table. The control group received pricking-bloodletting cupping at Dazhui (GV 14). The intervention group was administered acupuncture anesthesia at Hegu (LI 4) and Quchi (LI 11) bilaterally then pricking-bloodletting cupping at Dazhui (GV 14; Figure 1). Patients' age, sex, duration of disease, previous treatment for acne and other medical history were recorded and analyzed. Those collecting outcome data were not aware of the group allocation of participants, nor were they involved in treatment. Participants in both groups received pricking-bloodletting cupping and all participants were informed that the procedure they underwent comprised the complete acupuncture treatment for acne; thereby, the expectations of participants were the same in each group (Table 1).

Acupuncture and bloodletting procedure

Acupuncture anesthesia and pricking-bloodletting cupping were performed by a licensed acupuncturist with 5 years of clinical experience having graduated from a University of Chinese Medicine. Disposable stainless-steel acupuncture needles (0.30 mm × 40 mm, Huatuo Acupuncture, Suzhou, Jiangsu, China) were used. After perpendicular insertion, the patients experienced arrival of *Qi* [a needling sensation including soreness, numbness, heaviness or distention in the local region of Hegu (LI 4) and Quchi (LI 11)]. The needles were retained for 15 min. Then, a disposable plum-blossom needle (Single-head, Huanqiu Acupuncture, Suzhou, Jiangsu, China) was used to tap the Dazhui (GV 14) area 20 times until a small amount of bleeding occurred, then a cup (5 cm diameter Kangzhu vacuum cup, Beijing, China) was applied and retained for 10 min. At the end of treatment, the Dazhui (GV 14) area was disinfected again and covered with sterile gauze for about 3 h. Participants in the control group

Table 1 Comparison age, gender, duration, GAGS of patients in two groups ($\bar{x} \pm s$)

Group	n	Age (years)	Gender [female, n (%)]	Duration of acne (years)	GAGS score
Intervention	16	21.5±4.5 ^a	9(56.3) ^a	5.2±1.2 ^a	22.6±3.2 ^a
Control	16	20.1±5.6	8(50)	4.5±0.8	24.3±4.1

Notes: the intervention group was treated with acupuncture anesthesia at Hegu (LI 4) and Quchi (LI 11) first and then pricking-bloodletting cupping at Dazhui (GV 14); the control group was treated with pricking-bloodletting cupping at Dazhui (GV 14) only. GAGS: global acne grading system. Compared with the control group, ^aP>0.05.

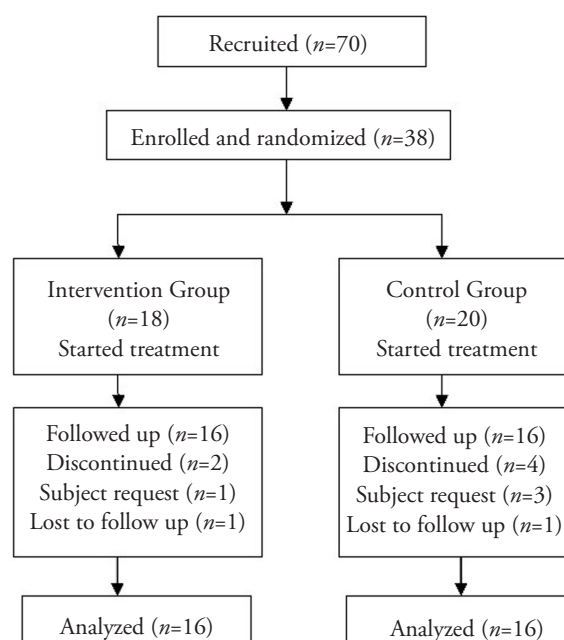


Figure 1 Flow chart of the trial

were treated with pricking-bloodletting cupping alone. Participants adopted the prone position throughout each treatment to avoid fainting, and were asked not to squeeze or press the papules and nodules afterwards. Only the data of those who completed the full course of treatment (twice weekly for 6 weeks, totaling 12 sessions) were included in the analysis.

Outcome measures

The pain experienced during the pricking of the Dazhui (GV 14) area by the plum-blossom needle was measured using a standard 100-mm visual analog scale [visual analog scale (VAS), 0=no pain, 100=worst pain ever].⁸ Participants noted their scores after each pricking-bloodletting cupping treatment. The 100 mm VAS was also used to evaluate the extent of the pain experienced in the pricked area after each treatment. The duration of pain was also recorded, having been obtained by cellphone text messages from the patients 3 h after treatment.

The therapeutic effect was evaluated using GAGS,⁹ which takes into account the area, distribution, and density of affected pilosebaceous units on the face, chest and upper back. The severity was graded as mild if the score was 1-18, moderate if the score was 19-30, severe if the score was 31-38, and very severe if the score exceeded 38.¹⁰ Before the treatment began, the GAGS score of each participant was calculated and those patients with scores 8-30 were recruited to the study. After 6 weeks of treatment, the single-blind researchers evaluated and recorded the severity of acne again using the GAGS score.

Safety monitoring

Safety was monitored by the use of clinical laboratory tests, measurement of vital signs, and observation and recording of adverse events. Clinical laboratory tests,

including routine hematological, biochemical and coagulation blood tests, were completed before the first treatment. The vital signs of each participant were checked before each time of treatment. Adverse events (including pain in the affected and Dazhui (GV 14) areas, nausea, vomiting, fatigue, dizziness, pallor, hematoma, allergic reaction, and any other adverse events related to acupuncture) were recorded after each treatment.

Statistical analysis

All the outcomes were analyzed using intention-to-treat (ITT) methodology. Missing data were replaced by data obtained at the last time of observation. Statistical analysis was undertaken using the Statistical Package for Social Sciences (SPSS version 11.5, International Business Machines Corporation, Armonk, New York, The United States of America) software thus: (a) continuous variables relating to subjects' baseline characteristics or other data were compared using an independent two-sample *t*-test or paired sample *t*-test; (b) categorical variables were compared using Pearson's *Chi*-squared test or Fisher's exact test if data were normally distributed; and (c) continuous variables are presented as mean \pm standard deviation (*SD*). $P < 0.05$ was considered to be statistically significant.

RESULTS

Seventy individuals responded to the advertisements, of whom 38 met the inclusion criteria. Of the 38 participants who began the study, 32 completed the course of treatment (16 in each group). Two patients in the intervention group dropped out, one was unable to tolerate the pain and the other was unable to keep the appointments for treatment. Four patients in the control group dropped out, three because of pain and one because of difficulty with scheduling. The dropout rate was 15.4% (Figure 1).

The baseline age, gender, duration and GAGS scores were shown in Table 1, and there were no differences between the two groups at baseline. There were no adverse events observed during acupuncture or cupping-bloodletting treatment.

The mean VAS score of pricking pain was 4.2 ± 1.0 in the intervention group and 8.0 ± 1.4 in the control group, a statistically significant difference. The mean VAS score of pain in the pricked area was significantly lower in the intervention group than in the control group (1.7 ± 0.3 for the intervention group and 3.0 ± 0.8 for the control group, $P < 0.01$). The mean duration of pain in the pricked area was (0.45 ± 0.06) h in the intervention group and (1.51 ± 0.37) h in the control group, which was also a statistically significant difference (Table 2).

The therapeutic effect of pricking-bloodletting cupping and acupuncture were also evident: to make a within-group comparison, the mean GAGS scores re-

Table 2 Changes in VAS scores of the two groups ($\bar{x} \pm s$)

Group	n	VAS scores of pricking pain	VAS scores of pricked area	Pain duration (h)
Intervention	16	4.18±1.01 ^a	1.71±0.25	0.45±0.06 ^b
Control	16	8.01±1.35	3.04±0.78	1.51±0.37

Notes: the intervention group was treated with acupuncture anesthesia at Hegu (LI 4) and Quchi (LI 11) first and then pricking-bloodletting cupping at Dazhui (GV 14); the control group was treated with pricking-bloodletting cupping at Dazhui (GV 14) only. VAS: visual analog scale. Compared with the control group, ^a $P < 0.01$; ^b $P < 0.05$.

duced in two groups after treatment. In the intervention group, GAGS scores recorded changes in mean scores from before treatment at 22.6 ± 3.2 to end of treatment at 8.3 ± 2.1 ($P < 0.01$ by paired sample t -test). In the control group, GAGS scores recorded changes in mean scores from before treatment at 24.3 ± 4.1 to end of treatment at 9.0 ± 1.9 ($P < 0.01$ by paired sample t -test). However, the statistical differences of GAGS scores between intervention and control group were not seen after treatment ($P > 0.05$ by independent two-sample t -test).

DISCUSSION

We found that acupuncture anesthesia effectively relieved the pain of pricking-bloodletting cupping during pricking and in the pricked area after treatment, and shortened the duration of pain in the pricked area. Reduction in GAGS scores was evident from baseline in both groups, but did not differ significantly between the groups after treatment had been completed.

Traditional Chinese Medicine attributes acne vulgaris to endogenous heat in the Lung, Spleen and Stomach meridians, to the exogenous toxin that makes blood-heat stagnate in the skin, and to overindulgence in fatty, sweet and pungent food that makes the spleen and stomach produce damp-heat that in turn affects the skin.¹¹ Bloodletting cupping at Dazhui (GV 14) can remove the toxin and blood-heat in the Governor vessel and Lung, Spleen and Stomach meridians.¹² It can also improve metabolism and nourishment of tissues, and promote the circulation of *Qi* and blood.¹³

The original description of bloodletting cupping therapy can be traced back to Huangdi's Internal Classic.¹⁴ There is a close relationship between the 12 cutaneous areas, 12 regular meridians and *Zangfu* organs.¹⁵ Thus plum-blossom needle tapping on the skin can regulate the functions of *Zangfu* organs, dredge the meridians, and harmonize *Qi* and blood. In addition, because most patients with acne vulgaris have symptoms of blood heat and stasis (such as papules and herpes or pustules and nodules, a purple tongue with petechiae, and a wiry and rapid pulse), blood-activating and stasis-resolving are important principles underpinning the rationale for treatment.

According to clinical observation, blood-activating and stasis-resolving can improve and regulate blood circulation and the function of vessels and nerves; therefore,

they can effectively modulate collagen metabolism and the endocrine system, and have a significant effect on blood circulation and connective tissue metabolism.¹⁵ Dazhui (GV 14) is the crossing point of all the *Yang* meridians of the hand and foot, where the *Yang-Qi* of the whole body gathers.¹⁶ Bloodletting cupping at Dazhui (GV 14) can remove blood-heat and stasis in the Governor vessel and *Yang* meridians. Previous studies have suggested this to be an effective means of treating patients with acne vulgaris,¹⁷ consequently Dazhui (GV 14) has been called the "acne point" in the literature.³⁻⁵ In this study, the GAGS score decreased significantly after treatment, meaning that our findings are consistent with that of previous studies. Participants in both groups received a similar amount of stimulation by plum-blossom needle tapping and experienced a similar amount of bleeding, explaining why the GAGS scores of the groups were not significantly different. To a certain extent, the amount of bleeding is positively correlated with the effect of treatment.^{18,19} Increasing the amount of stimulation by using a three-edged needle for pricking, or a plum-blossom needle for tapping to get the optimal amount of bleeding achieves a better result, but consequently many patients find the pain of the procedure intolerable. This can be addressed by acupuncture anesthesia.

Acupuncture anesthesia is a needling method used to facilitate invasive procedures in conscious patients. It is simple, convenient, safe, and does not require complicated or expensive instruments or devices. During the procedure, little or no analgesia is needed, thus the patient is exposed to few of the risks and none of the side effects of anesthetic or analgesic drugs.²⁰ The patient remains alert, with normal motor function, but experiences hypoalgesia in the treatment area. After the procedure, the patient experiences only mild pain without nausea and vomiting, and can soon eat, drink and walk. Acupuncture anesthesia may also be used for surgery to the thyroid, maxillary sinus, eye, cranium, cervical vertebrae and other areas,²¹ but is rarely used for bloodletting, scarring moxibustion and bone-setting in Traditional Chinese Medicine manipulations, as the traditional concept is that the patient must be in pain beforehand.

In this study, a significant therapeutic effect of acupuncture anesthesia was observed after a 15 min manipulation at Hegu (LI 4) and Quchi (LI 11). The anesthetic effect lasted 2-3 h, affording significant post-manipulation analgesia, reducing both the

amount and duration of pain reported. As well as providing anesthesia, puncturing Hegu (LI 4) and Quchi (LI 11) can clear heat from Yangming, which is an important aspect of the treatment of acne;²² however in this study, puncturing these points had no additional therapeutic benefit to pricking-bloodletting cupping at Dazhui (GV 14) alone. Traditional Chinese Medicine holds that acne vulgaris is caused by excess endogenous heat in the Lung, Spleen and Stomach meridians. Nevertheless, puncturing Hegu (LI 4) and Quchi (LI 11) does not substantially clear heat, while bloodletting cupping at Dazhui (GV 14) can directly remove toxins and blood-heat. Of the two, the former only appears to play a role in acupuncture anesthesia, while the latter has the predominant therapeutic benefit.

Limitations of this study include its small size, the lack of an untreated control group. The intervention group did not only receive treatment to Dazhui (GV14) but also puncture Hegu (LI 4) and Quchi (LI 11) points that would have been expected to have both anesthetic and therapeutic effects, but our clinical trial was lack of the only acupuncture on Hegu (LI 4) and Quchi (LI 11) group.

Acupuncture anesthesia at Hegu (LI 4) and Quchi (LI 11) is an effective means of relieving the pain of pricking-bloodletting cupping and the pricked area, and reduced the duration of pain in the treated region. Pricking-bloodletting cupping at Dazhui (GV 14) improves skin lesions in the patients with moderate acne vulgaris, but acupuncture anesthesia itself shows no intrinsic therapeutic benefit.

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